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|--|-------------|----------------------|---------------------|------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/990,586   | 11/21/2001  | Hing C. Wong         | 71758/46943-CIP2    | 2050             |
| 21874  | 7590        | 11/05/2003           | EXAMINER            |                  |
| EDWARDS & ANGELL, LLP<br>P.O. BOX 9169<br>BOSTON, MA 02209 |             |                      | HADDAD, MAHER M     |                  |
|  |             | ART UNIT             | PAPER NUMBER        |                  |
|  |             | 1644                 | 12                  |                  |
| DATE MAILED: 11/05/2003                                    |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |              |
|------------------------------|-----------------|--------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s) |
|                              | 09/990,586      | WONG ET AL.  |
|                              | Examiner        | Art Unit     |
|                              | Maher M. Haddad | 1644         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 07 July 2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-72 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-72 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

    1. Certified copies of the priority documents have been received.

    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

    a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .      6) Other: \_\_\_\_\_ .

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-58 and 62, drawn to a humanized antibody that binds specifically to human tissue factor (TF), comprises HC-FR1-4, HC-CDR1-3, LC-FR1-4, LC-CDR1-3, HC constant sequence, LC constant region, fragments thereof and a composition thereof, classified in Class 530, subclasses 387.3 and 388.25 and Class 424, subclass 131.1.
  - II. Claims 59-61 and 68, drawn an isolated nucleic acid encoding at least one of the heavy or light chain of humanized antibody that binds specifically to human tissue factor, recombinant vectors and host cells; classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
  - III. Claims 63-66, drawn to a method of inhibiting blood coagulation in a mammal with a humanized antibody that binds specifically to human tissue factor; classified in Class 424, subclasses 133.1 and 141.1.
  - IV. Claim 67, drawn to a method of detecting tissue factor in a biological sample with a humanize antibody that binds specifically to human tissue factor, classified in Class 435, subclass 7.1.
  - V. Claims 69-72, drawn to a method for producing a humanized antibody comprises comparing amino acid sequences, selecting a human framework sequence, mutagenizing a DNA segment and assembling into a vector, classified in Class 435, subclasses 69.1, 455, 325, 326 and 337.
2. Groups I and II are different products. Nucleic acids and antibodies differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.
3. Groups III-V are different methods. A method of inhibiting blood coagulation, a method of detecting and a method for producing differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.
4. Groups I and III-IV are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group I can be used for affinity purification, in addition to the methods of inhibiting and detecting recited.
5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods

of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

*Species Election*

6. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

- A. If any one of Groups I-III is elected, applicant is required to elect a humanized antibody that binds specifically to TF, wherein:
  - 1. the LC constant region is SEQ ID NO: 97 or 99,
  - 2. HC constant region is SEQ ID NO: 98 or 100,
  - 3. the antibody has an IgG1 (hOAT) or IgG4 (hFAT) isotype,
  - 4. HC CDR2 is SEQ ID NO: 90 or 101,
  - 5. the HC FR1 is FR1 in SEQ ID NO: 91 or a specific change such as in claim 28,
  - 6. the HC FR2 is FR2 in SEQ ID NO: 91 or a specific change such as in claim 30,
  - 7. the HC FR3 is FR3 in SEQ ID NO: 91 or a specific change such as in claim 32,
  - 8. the HC FR4 is FR4 in SEQ ID NO: 91 or a specific change such as in claim 34,
  - 9. the LC FR1 is FR1 in SEQ ID NO: 79 or a specific change such as in claim 36,
  - 10. the LC FR2 is FR2 in SEQ ID NO: 79 or a specific change such as in claim 38,
  - 11. the LC FR3 is FR3 in SEQ ID NO: 79 or a specific change such as in claim 40,
  - 12. the LC FR4 is FR4 in SEQ ID NO: 79 or a specific change such as in claim 42,
- these are distinct species because their structures and physicochemical properties are different, thus each represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of

an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9307.

Maher Haddad, Ph.D.  
Patent Examiner  
Technology Center 1600  
October 27, 2003

  
CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600